MTP Medical Technology Program

U.S. Department of Energy

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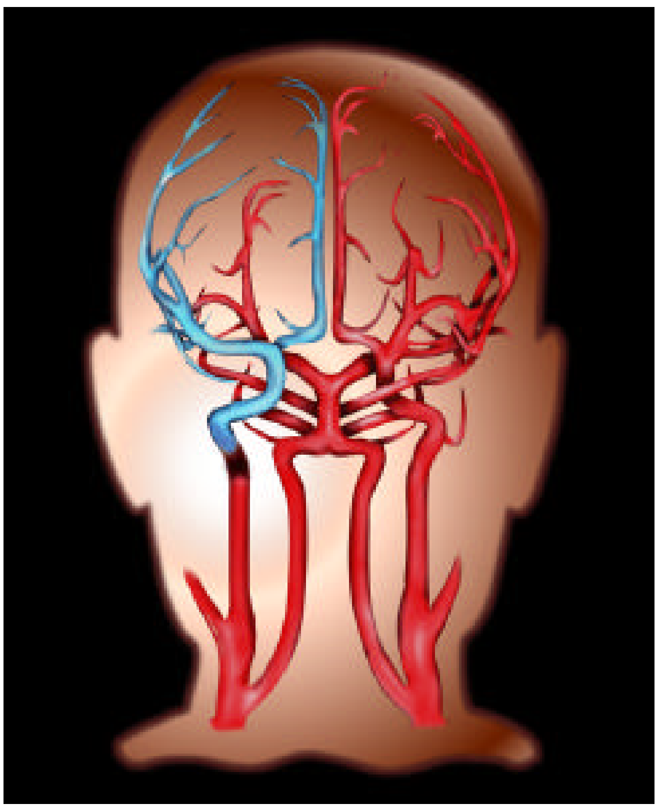
Endovascular Photo-Acoustic Recanalization as a Treatment for Stroke

Stroke

Researchers at the Lawrence Livermore National Laboratory are attacking the problem of stroke with new tools to restore blood flow. Stroke is the third leading cause of death (150,000/year) and the leading cause of disability in the United States. Approximately 700,000 strokes occur annually in the U.S., accounting for costs of over $26 billion/year for treatment and rehabilitation. Worldwide, 4.5 million deaths per year are attributed to stroke. Ischemic, or vascular occlusion, strokes account for approximately 80% of strokes; hemorrhage makes up the remainder.



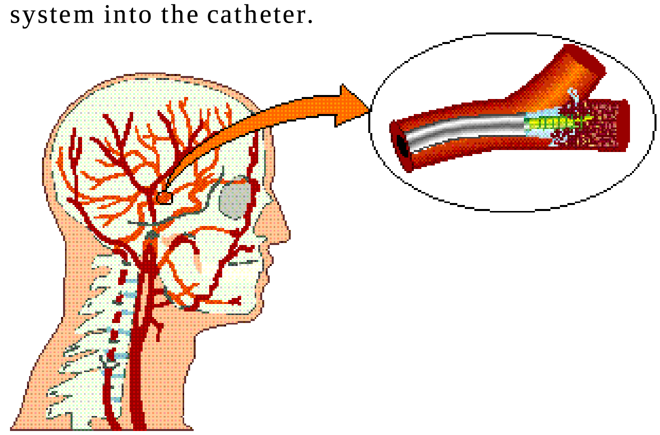
Stroke is the 3rd leading cause of death in the United States. The above illustration shows a blockage in the carotid artery, which is preventing blood flow to areas of the brain.

It is imperative that a patient experiencing a stroke seek medical attention immediately as there is roughly a two-to-four hour window in which to resolve the clot before permanent neurological impairment may result.

Current treatment modalities include mechanical intervention or pharmacologic thrombolytic (drug) therapy to disrupt or dissolve thrombus (blood clots). Current mechanical interventions can be relatively invasive and are limited in their accessibility to larger vessels, for example carotid arteries. However, most occlusions occur in smaller, more deeply-seated vessels such as the middle cerebral artery. Thrombolytic therapy may be effective but thrombolytics are not indicated for all stroke victims, are not effective on all thrombus, and have associated risks, some of which may have severe consequences, particularly hemorrhage. Successful development of a new treatment modality could have significant benefits to the outcomes of stroke patients, ultimately improving mortality rates and decreasing morbidity, thereby decreasing the cost of rehabilitation and improving the quality of life in stroke patients.

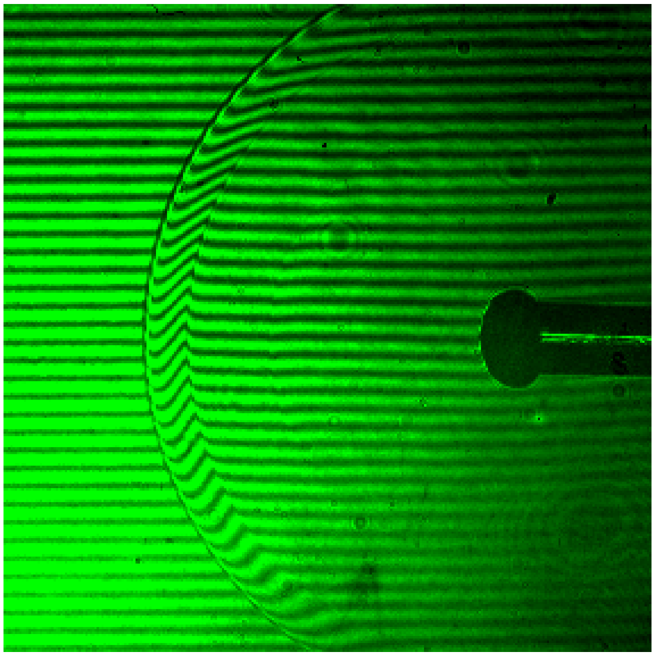
Endovascular Photo-Acoustic Recanalization

Researchers at LLNL have developed unique technologies to aid in the disruption of thrombus occlusions. This minimally invasive technique, Endovascular Photo-Acoustic Recanalization (EPAR), involves guiding a catheter to the site of the occlusion and introducing an optical fiber delivery system into the catheter.



Endovascular Photo-Acoustic Recanalization. The device is inserted through a guiding catheter, permitting delivery to a variety of locations. Laser energy disrupts the clot.

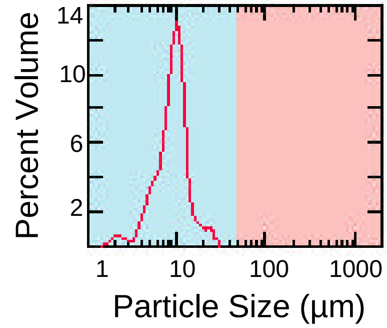
Laser light is coupled into the optical fiber and delivered to the occlusion, causing mechanical disruption of the occlusion and re-establishing blood flow to the brain. The mechanism of interaction involves depositing laser energy into blood or blood clot, creating an acoustic wave, which is transmitted into the clot, and a subsequent vapor bubble.



A picture of a stress wave and vapor bubble created by the deposition of laser energy through an optical fiber.

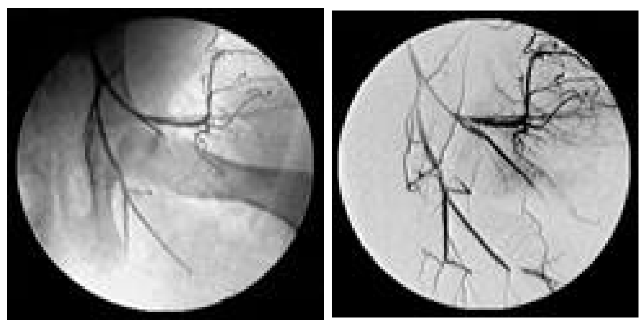
The size of the fiber and catheter allow for treatment of occlusions in small diameter cerebral arteries, less than 3 mm. The limited amount of power required and the specific nature of laser-interaction have thus far proven to be atraumatic to blood vessels and surrounding tissues. Additionally, the duration of the entire procedure should be significantly shorter than thrombolytic therapy.

Initial development of the laser and delivery system were performed at LLNL, incorporating computer modeling and experimentation. Computer models effectively aided in optimizing irradiation parameters and predicted thrombus-material failure modes. Parametric laboratory experiments were performed to determine optimal laser irradiation parameters for safe and effective clot emulsification. Experiments ranged from studying the pressure and temperature effects of single laser events to testing the feasibility of laser-assisted thrombolysis *in vivo*. *In vitro* studies indicated that clots could be emulsified into particles that should pass unobstructed through the vasculature.



Experiments indicate that particles resulting from the endovascular photo-acoustic recanalization treatment are small enough to pass through the vasculature.

The technology was licensed to EndoVasix, Inc. in November of 1996 and development continued in parallel at LLNL and at EndoVasix. EndoVasix has tested the device in animal studies, which showed positive results. EndoVasix will further advance designs for eventual investigations in humans in Europe in 1998.



Angiograms from EndoVasix animal trials. The circled region in the left angiogram shows an obstruction of blood flow. On the right, endovascular photo-acoustic recanalization has restored blood flow to this area.

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